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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/609,146	06/30/2000	James A. Bonini	60794-B/JPW/KRD	2958

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EXAMINER
O HARA, EILEEN B

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 05/28/2002 13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/609,146	BONINI ET AL.	
	Examiner	Art Unit	
	Eileen B. O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *235-281* is/are pending in the application.

4a) Of the above claim(s) *252, 253, 264, 265 and 272-275* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *235-251, 254-263, 266-271 and 276-281* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *235-281* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,5,6,7,8*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 235-281 are pending in the instant application.

Election/Restrictions

2. Applicant's election with traverse of Group I in Paper No. 12 is acknowledged. The traversal is on the ground(s) that:

35 U.S.C. §121 states, in part, that "[I]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.", and under M.P.E.P. §802.01, "independent" means "there is no disclosed relationship between the ... subjects disclosed, that is, they are unconnected in design, operation, or effect... ."

Applicants assert that two independent and distinct inventions have not been claimed in the subject application, because the groups are not independent under M.P.E.P. §802.01. Additionally, Applicant points out that M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden."

Applicants maintain that there would not be a serious burden on the Examiner if restriction were not required, and a search of prior art with regard to any of one group identified by the Examiner would necessarily identify art for the other groups.

This is not found persuasive because under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to

support separate patents and they are either independent (MPEP § 806.04- § 806.04(I)) **or** distinct (MPEP § 806.05-§ 806.05(I)).

Under MPEP § 803, there are two criteria for a proper requirement for restriction between patentably distinct inventions:

(A) The inventions must be independent (see MPEP § 8702.01, 806.04, 808.01) **or** distinct as claimed (see MPEP § 806.05 - § 806.05(I): and

(B) There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a) - § 806.04(I), § 808.01(a), and § 808.02).

The term "distinct" means that two or more subjects as disclosed are related, for example, as combination and part (subcombination) thereof, process and apparatus for its practice, process and product made, etc., but are capable of separate manufacture, use or sale as claimed, **and are patentable** (novel and unobvious) **over each other** (though they may each be unpatentable because of the prior art). It will be noted that in this definition the term related is used as an alternative for dependent in referring to subjects other than independent subjects. (MPEP § 802.01). Where inventions are related as disclosed but are distinct as claimed, restriction may be proper (MPEP § 806(B)).

Consistent with current patent practice, a serious search burden may be established by (A) separate classification thereof: (B) a separate status in the art when they are classifiable together: (C) a different field of search:. These criteria were met in the above restriction. Further, a search is directed not only to art which would be anticipatory, but also to art that would render the invention obvious. Thus, the three groups require divergent searches, and to search all three inventions would be burdensome. Therefore, the restriction is maintained.

The requirement is still deemed proper and is therefore made FINAL.

Claims 252, 253, 264, 265 and 272-275 are withdrawn as being drawn to a non-elected invention.

Claims 235-251, 254-263, 266-271 and 276-281 are currently under examination.

Corrected Filing Receipt

3. The request for correction of filing receipt filed May 3, 2001 has been entered.

Information Disclosure Statement

4. The sequences disclosed in the IDS filed June 30, 2000 have not been considered. Without an explanation of relevance or a sequence alignment, the relevancy of the sequences cannot be determined.

Priority

5. This application filed under former 37 CFR 1.60 lacks the current status of the nonprovisional parent applications 09,558,099 and 09/466,435. A statement reading "(now abandoned)" should be included after the filing dates in the first sentence of the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6.1 Claims 235-251, 254-263, 266-271 and 276-281 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification discloses two polypeptide sequences consisting of SEQ ID NOS: 4 and 25, identified as SNORF72 receptors, which are human and rat orthologs that are 79.5% identical and which are shown to have the following activities: binding neuromedin U (NMU) neuropeptides and stimulation of intracellular Ca^{2+} release upon binding. However, the claims as written encompass using any mammalian SNORF72 receptor to screen for compounds that interact with the receptor. The instant disclosure of two polypeptide orthologs, that of SEQ ID NOS: 4 and 25 with the instantly disclosed specific activities, does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera. A genus claim may be supported by a representative number of species as set forth in *Regents of the University of California v Eli Lilly & Co,* 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), which states:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention". Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1980) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.") Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d 1565, 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id at 1170, 25 USPQ2d at 1606."

A description of a genus of SNORF72 receptors may be achieved by means of a recitation of a representative number of SNORF72 receptors, defined by polypeptide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. The instant specification discloses, however, only two isolated polypeptide sequences, SEQ ID NOS: 4 and 25. It cannot be established that a representative number of species have been disclosed to support the genus claim. No activity is set forth for the mammalian SNORF72 receptor, other than that of using it in competitive binding experiments with a chemical compound known to bind the receptor but not identified in the claims as having any particular structure or function.

Because the specification merely discloses two orthologs, and does not describe any other, the written description requirement has not been met.

The term "SNORF72 receptor" encompasses any protein that has the activities described in the specification. Because claims 235-251, 254-263, 266-271 and 276-281 recite a functional limitation in the absence of any structural limitations, it is a single means claim which encompasses any protein which can function as a receptor to which any compound of unknown structure can bind. A single means claim, i.e., where a means recitation does not appear in

combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph. In re Hyatt , 708 F.2d 712,>714 - 715,< 218 USPQ 195>, 197< (Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.). When claims depend on a recited property, a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. See M.P.E.P. 2164.08(a)

Whereas the instant specification provides a detailed description of SNORF72 proteins having very specific physical and structural properties, the instant specification does not identify those defining structural elements which provide the functional and structural properties which is definitive of mammalian SNORF72 receptors

6.2 Claims 276-281 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims encompass a process for preparing a composition which comprises identifying a chemical compound that binds to or is an antagonist to a mammalian SNORF72 receptor, and admixing that chemical compound or a novel structural and functional analog or homolog thereof, with a pharmaceutically acceptable carrier. The specification has not described what a novel structural and functional analog or homolog of such a binding or antagonist compound would look like, and therefore does not meet the written description requirement.

Conclusion

7. No claim is allowed.

The art considered pertinent to the present application is Behan et al., WO 00/22131A1 (cited by Applicants), which discloses a polypeptide identified as a human G protein-coupled receptor (see pages 86-87), which is 100% identical to the polypeptide of SEQ ID NO: 4 of the present application. Although the publication date of the reference precedes the priority date of the present application, Behan et al. did not appreciate that their polypeptide was a receptor for neuromedin U neuropeptides.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

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